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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/535,521 | 05/18/2005 | Michael R. Emmert-Buck | 4239-73127-03 | 7250 |

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| EXAMINER | |
|---|---|
| CALAMITA, HEATHER | |
| **ART UNIT** | **PAPER NUMBER** |
| 1637 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/535,521 | EMMERT-BUCK ET AL. | |
| | Examiner | Art Unit | |
| | Heather G. Calamita, Ph.D. | 1637 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *05 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *8 and 15-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 9-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of Application, Amendments, and/or Claims*

1. Amendments of June 5, 2007, have been received and entered in full. Claims 1-24 are pending. Claims 8 and 15-24 are withdrawn as being directed to non-elected subject matter. Claims 1-7 and 9-14 are under examination. All arguments have been fully considered and thoroughly reviewed, but are deemed not persuasive for the reasons that follow. Any objections and rejections not reiterated below are hereby withdrawn.

### *Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7 and 9-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Warrington et al. (Us 2001/0044104 A1).

With regard to claim 1, Warrington et al. teach a method for analyzing the transcriptome of a cellular sample comprising:

analyzing two or more molecular species present in a 2-dimensional array of said cellular sample, wherein said method comprises treating said 2-dimensional array with an External Movement Inhibitor device having multiple discrete partitions, wherein the multiple discrete partitions comprise at least one of a plurality of grids or a plurality of wells, so as to sequester molecules present in said array into one or more discrete regions, wherein said treatment preserves the positional relationship of the

molecules of said 2-dimensional array, and permits a determination of the location(s) in said cellular sample in which said molecular species are present (see paragraph 0031, where RNA meets the limitation of transcriptome and the microwell array is a 2D array. The partitions between each of the wells in the microwell array serves as an external movement inhibitor because the partition prevents the movement of the RNA on the array. The partition additionally keeps the RNA in one or more discrete regions on the membrane and permits determination of the location of the cDNA probes (molecular species) on the array).

With regard to claim 2, Warrington et al. teach wherein said cellular sample is a cellular sample obtained from a mammal (see paragraph 0104, where Warrington teaches the tissue sample may be from a woman).

With regard to claim 3, Warrington et al. teach the mammal is a human (see paragraph 0104, where Warrington teaches the tissue sample may be from a woman).

With regard to claim 4, Warrington et al. teach the cellular sample is a tissue sample (see paragraph 0104, where Warrington teaches the tissue sample may be from a woman).

With regard to claim 5, Warrington et al. teach the tissue sample is a biopsy (see paragraph 0104, where Warrington teaches sample is a biopsy of endometrial tissue from women).

With regard to claim 6, Warrington et al. teach the molecular species are nucleic acid molecules (see paragraph 0106, where cDNA, RNA or DNA can be the molecular species).

With regard to claim 7, Warrington et al. teach the method additionally comprises incubating the sequestered nucleic acid molecules of two or more regions under conditions sufficient to permit the manipulation of one or more preselected nucleic acid molecules if present at said regions, while preserving the positional relationship of said molecules relative to other molecules of said 2-dimensional array (see paragraph 0133, where the DNA probes are in discrete regions, and manipulated with the binding of RNA sample. Warrington et al. do not exemplify hybridization in microwells, however

Warrington et al. disclose microwells can be used in the gene expression monitoring experiments and if microwells are used the fluorescence of the labeled RNA to the probes within the well would indicate the positional relationship of the molecules is preserved relative to other molecules on the array).

With regard to claim 9, Warrington et al. teach one or more of the preselected nucleic acid molecules are diagnostic of a disease state (see paragraph 0133 where cancer is the disease state).

With regard to claim 10, Warrington et al. teach the manipulation is assaying a biomolecule (see paragraph 0133 where RNA hybridizing to probes in an array is assaying a biomolecule).

With regard to claim 11, Warrington et al. teach incubating the sequestered nucleic acid molecules of all of the regions under conditions sufficient to permit the manipulation of said one or more preselected nucleic acid molecules (see paragraph 0133 where RNA hybridizing to probes in an array is assaying a biomolecule. Additionally as hybridization of the RNA probes to the DNA occurs; the conditions are sufficient for the manipulation).

With regard to claim 12, Warrington et al. teach the one or more preselected nucleic acid molecules are diagnostic of a disease state (see paragraph 0133 where cancer is the disease state).

With regard to claim 13, Warrington et al. teach the manipulation is assaying a biomolecule (see paragraph 0133 where RNA hybridizing to probes in an array is assaying a biomolecule).

With regard to claim 14, Warrington et al. teach the cellular sample is an extract of a cell and the 2D array is a gel or membrane that arrays the nucleic acid molecules (see paragraph 0127, where Warrington teaches the RNA was derived from tissue samples. Tissues are made from cells and RNA is isolated from a cell extract. See paragraph 0127 where Warrington teaches the DNA is arrayed on a nylon membrane).

***Response to Arguments***

5. Applicants' arguments with respect to claims 1-7 and 9-14 have been considered but are moot in view of the new ground(s) of rejection. With respect to the 102 (b) rejection, Applicants arguments are

irrelevant in view of the new rejection made over Warrington. Applicants amended claim 1 to recite "wherein the multiple discrete partitions comprise at least one of a plurality of grids or a plurality of wells" and Rutanen does not teach this claim limitation therefore the rejection was withdrawn and new rejections over Warrington were applied. Applicants additionally request rejoinder of the product claims with the withdrawn method claims. Currently the claims drawn to the product are not in condition for allowance therefore the claims will not be rejoined. The issue of rejoinder will be considered at which time the claims are deemed to be in condition for allowance.

***Conclusion***

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Correspondence***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 5:30 PM.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at 571.272.0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number 571.273.8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to 571.272.0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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